UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PLAINTIFFS' ENGINEERING EXPERTS DANIEL KOENIGSHOFER, MICHAEL BUCK, SAID ELGHOBASHI, AND YADIN DAVID

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INTRODUCTION

Plaintiffs' engineering experts Daniel Koenigshofer, Michael Buck, Said Elghobashi, and Yadin David[1]—collectively, "Plaintiffs' engineers"—did not test the one question at the heart of their general causation opinions: Does the Bair Hugger system cause bacteria to reach a patient's surgical site? Instead, they rely on flawed assumptions, invalid inferences, and the junk science fomented by Dr. Scott Augustine to disparage the Bair Hugger system. Plaintiffs' engineers' general causation opinions are therefore scientifically unreliable and should be excluded under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). They should also be excluded in the Ramsey County cases because they lack foundational reliability and are not "generally accepted" as required by Minnesota's *Frye-Mack* standard.

Against the weight of medical opinion—including, most recently, the FDA's recommendation to "continue[] . . . the use of thermoregulating devices (including forced air thermal regulating systems)"—Plaintiffs' engineers claim that the Bair Hugger system is capable of causing surgical infections. They offer two theories of how this might occur:

1. **The "Reservoir of Infection" Theory.** The engineers claim that the Bair Hugger "vacuums" bacteria from the operating room floor, passes it through an inadequate filter, and delivers it to the surgical site.

[1] Dr. David's opinions regarding regulatory matters, purported safer alternative designs, and Defendants' "state of mind" are addressed in a separate, contemporaneously filed motion. The present motion is limited to David's general causation opinions.

2. **The "Airflow Disruption" Theory.** The engineers claim that warm air emitted from the Bair Hugger blanket "disrupts" operating room airflow, stirs up bacteria, and causes them to fall into the surgical site.

The engineers did not devise these theories themselves—Dr. Augustine developed and promoted them years ago. Moreover, they have failed to show that either theory has any validity.

In addition to relying on Dr. Augustine's work, Plaintiffs' engineers conducted experiments to count particles emitted from the Bair Hugger system, and developed a computer simulation of the system's purported impact on operating room airflow. But neither the experiments nor the computer model is capable of showing that the Bair Hugger system actually causes bacteria to reach the surgical site. Mr. Buck's experiments counted *particles* emitted from the Bair Hugger hose and blanket, but did not attempt to find any *bacteria* among those particles. Plaintiffs' purposeful avoidance of bacteria may well have been driven by the numerous published studies—and secret *un*published studies by Dr. Augustine's cohorts—showing that use of the Bair Hugger system does *not* increase bacteria.

As for Plaintiffs' computer model, it relies entirely on assumptions that do not reflect what actually happens in the real world. Instead of measuring the temperature and velocity of warmed air emerging from the surgical drapes, Dr. Elghobashi—who supplied the "boundary conditions" on which the model is based—"substituted by thinking hard." Not surprisingly, the results of his "thought experiment" do not agree with actual temperature readings taken by other experts, including Dr. David. Because the model has

not been validated by a real-world experiment, it lacks the "indicia of reliability" that *Daubert* demands, and must therefore be excluded. *Gier By & Through Gier v. Educ. Serv. Unit No. 16*, 66 F.3d 940, 942 (8th Cir. 1995) (affirming exclusion of experts whose methodology "lacked sufficient indicia of reliability under *Daubert*").

While all of Plaintiffs' engineers share their reliance on Dr. Augustine's flawed mechanistic theories, each has his own separate bases for exclusion, including lack of qualifications, unreliable methodology, lack of "fit," and a tendency to confuse and mislead the jury. Fed. R. Evid. 402, 403, and 702; *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (explaining *Daubert*'s requirement of "fit"). Because the engineers' opinions do not meet these standards, their testimony must be excluded.

The analytical gaps and flawed assumptions in Plaintiffs' theories are not mere fodder for cross-examination. Rather, the theories are "so fundamentally unsupported that [they] can offer no assistance to the jury." *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 929–30 (8th Cir. 2001). Plaintiffs' engineers' testimony and opinions must therefore be excluded in their entirety.

FACTS

I. PLAINTIFFS' MECHANISTIC THEORIES COME STRAIGHT FROM DR. AUGUSTINE'S CAREFULLY ORCHESTRATED PLAYBOOK.

As noted, Plaintiffs' engineers are not the authors of the "Reservoir of Infection" and "Airflow Disruption" theories. Dr. Augustine invented those concepts many years ago as part of his strategy to promote his new warming device, the HotDog, by raising

suspicions about the safety of the Bair Hugger system.[2] Dr. Augustine was motivated to develop the HotDog by his former colleagues' refusal to reimburse the $2,000,000 fine he paid as a result of his guilty plea.[3] The Augustine/Arizant imbroglio was tried to a jury in early 2007, and eventually found its way to the Minnesota Supreme Court.[4]

In October 2007—less than three months after the Minnesota Court of Appeals reversed Augustine's trial victory over Arizant[5]—he launched a campaign against the Bair Hugger entitled "Blowing Air is Risky" ("BAIR"). The circular he developed for the BAIR campaign included the large-print heading "**Reservoirs of Infection**," and alleged that "Recent studies show that the air-flow paths of Bair Hugger blowers are frequently contaminated with bacteria."[6] At around the same time, Augustine tasked a young employee and University of Minnesota graduate student, Mark Albrecht, with a suite of

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[2] Dr. Augustine's role as the original inventor of the Bair Hugger system, his ouster from the company he founded, and his conviction for Medicare Fraud are discussed in Defendants' brief in support of Motion to Compel Production of Documents on Augustine's Privilege Log (Doc. 130).

[3] *See* "Just Invent It," *Upsize MN*, http://www.upsizemag.com/cover-story/just-invent-it (last visited August 24, 2017).

[4] *See Scott D. Augustine, M.D. v. Arizant, Inc.*, 751 N.W.2d 95 (Minn. 2008).

[5] *See Scott D. Augustine, M.D. v. Arizant, Inc.*, 735 N.W.2d 740 (Minn. App. 2007).

[6] Augustine Deposition Exhibit 2 (DX 4) (Exhibits are attached to the Affidavit of Peter J. Goss filed herewith). Dr. Augustine borrowed the "Reservoirs of Infection" phrase from an article published in *Kentucky Epidemiologic Notes and Reports*, in which the author mentioned "Bair Hugger temperature management units" (along with ventilators, mattresses, curtains, and cell phones) as potential "reservoirs of infection." Beavers S., "Acinetobacter Infections among Hospitalized Patients in Kentucky-2006" 42 *Kentucky Epidemiologic Notes & Reports* (2007), identified as 3MBH00000932 (DX 5) at 3. The author later issued a clarification that she "did not find an association between *Acinetobacter* infection and Bair Hugger or forced air system use[.]" 3MBH00007909 (DX 6).

research intended to generate safety concerns about the Bair Hugger system. This work would eventually blossom into what Albrecht boastfully called "The Publication Factory."[7]

A. Augustine Hatches "Crud and Bug" Research While Albrecht Fails to Find Airborne Bacteria in Secret Tests.

To develop the "Reservoir of Infection" theme, Augustine and Albrecht developed a series of articles seeking to highlight the presence of bacteria in Bair Hugger units. These "crud and bug" papers, as Albrecht referred to them,[8] were ultimately published as:

- Albrecht M., et al., "Forced-air warming: a source of airborne contamination in the operating room?" *Orthopedic Reviews* (2009) (DX 1).
- Albrecht M., et al., "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *Am. J. Infec. Control* (2011) (DX 2).
- Reed M, et al., "Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions" *AANA Journal* (2013) (DX 3).

These papers reported bacteria in samples swabbed or rinsed from the interior surfaces of Bair Hugger warming units and hoses. They also counted particles coming out of the Bair Hugger system, and questioned the efficiency of the Bair Hugger filters. As the articles' titles make clear, Albrecht and his co-authors wanted readers to believe that the "particles" detected in the air were actually *bacteria*, like the bacteria they found by swabbing and rinsing the system's interior surfaces. But Albrecht *did not disclose* that he

[7] *See* July 9, 2010 email by Albrecht with subject, "Publication Factory Continues," Nachtsheim_0000838 (DX 7). At his deposition, Albrecht explained that he considered the "Publication Factory" to be "a point of pride, that we can produce research at a rate like that." Deposition of Mark Albrecht, Vol. 2 ("Albrecht Dep.") (DX 8) at 329:3–5.

[8] *See, e.g.*, Litchy_0000705 (DX 9) and Nachtsheim_0000118 (DX 10)

had made several attempts to detect bacteria in the air coming from the hose, and all of them *failed*.

Using multiple techniques, including an "impaction sampler" that injected air directly from the Bair Hugger hose on to agar plates,[9] Albrecht found *no increase* in bacterial colony-forming units (CFUs) at *any* of the five hospitals where he tested Bair Hugger units.[10] These undisclosed negative results *directly contradict* the articles' implication that the units were emitting large quantities of bacteria. Likewise, two of Albrecht's co-authors on the "crud and bug" papers, Dr. Reed and Dr. McGovern, *never disclosed* that they had conducted a carefully planned microbiology experiment in their operating room, and found no increase in bacteria with the Bair Hugger switched on. This second nondisclosure will be discussed further below.

B. Augustine Pivots to "Airflow Disruption" and Funds a Secret Microbiology Study.

While pursuing the "crud and bug" angle, Augustine and Albrecht began to explore another way to link the Bair Hugger to contamination fears, by promoting the theory that warm air from the Bair Hugger blanket could "disrupt" hospital HVAC[11] systems and stir up contamination in the OR. This mechanism was long familiar to Dr. Augustine; in fact,

[9] An "agar plate" is a type of Petri dish containing nutrients that promote bacterial growth. *See* Laboratory News, "History of the Agar Plate," https://www.labnews.co.uk/features/history-of-the-agar-plate-01-11-2005/ (last visited August 27, 2017).

[10] *See* Augustine Deposition Exhibit 8 (DX 11) at 20–28.

[11] "HVAC" is an acronym for "Heating, Ventilation, and Air Conditioning."

he anticipated it (and attempted to refute it) in a 1989 advertisement for the Bair Hugger.[12] In the ad, he reassured customers that the Bair Hugger system has no deleterious effect on OR airflow:

> **Localized Air Flow**
>
> The combination of the Steridrape™ (3M, St. Paul, MN) barrier design and the overlaying surgical drape, **prevents the warm exhaust air from migrating toward the surgical incision.**[13]

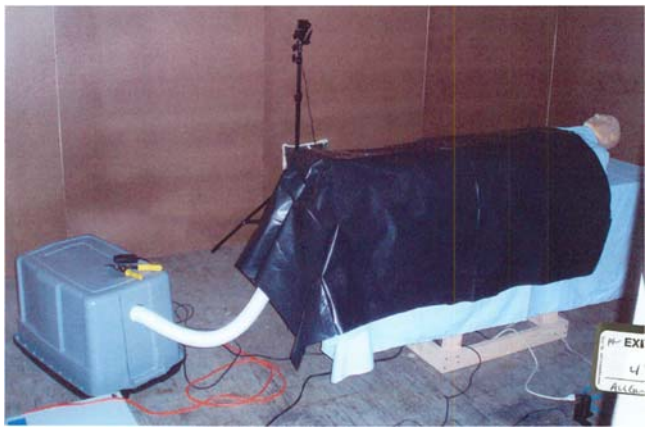
He included the following graphic to show that air from the Bair Hugger blanket is easily overwhelmed by the large volume of air from the operating room's ceiling diffusers:

But Dr. Augustine reversed course twenty years later. In 2009, he developed a video purporting to demonstrate the disruptive effects of the Bair Hugger on operating room

[12] 3MBH00047482 (DX 12).

[13] *Id.* (emphasis added).

airflow. He did not film the video in an actual operating room, but in a mock-up at the company's Eden Prairie warehouse, depicted here:[14]



The video shows patterns of smoke illuminated by a green laser beam.[15] A narrator delivers the punch-line: "In summary, this study reveals that forced-air warming destroys the protection of laminar flow, allowing contaminants to be dumped into the surgical wound."[16]

Dr. Augustine sent copies of the video to friends and former colleagues,[17] and he posted it on YouTube.[18] Dr. Mike Reed, an orthopedic surgeon in Northern England, saw the video in 2009.[19] Around that time, Dr. Reed's hospital was receiving letters from the British National Health Service indicating that it was a "high outlier" for infection rates in

[14] Augustine Dep. Exhibits 39, 46; *see also* Augustine Dep. Exhibits 47–49 (DX 13).

[15] *See* https://www.youtube.com/watch?v=hdtiBgUFzdc (last visited August 24, 2017).

[16] *Id.*

[17] *See, e.g.*, AUGUSTINE_0035140 and AUGUSTINE_0020049 (DX 14).

[18] *See* https://www.youtube.com/watch?v=hdtiBgUFzdc (last visited August 24, 2017).

[19] Deposition of Dr. Michael R. Reed ("Reed Dep.") (DX 15) at 26:3–10.

total hip and knee surgeries.[20] Reed discussed the video with Dr. David Leaper, a co-author on Albrecht's first "crud and bug" paper and a paid Augustine consultant.[21] In late 2009, Dr. Reed and Dr. Leaper, with £5,000 in funding from Dr. Augustine, collaborated on a microbiology study to examine whether use of the Bair Hugger influenced bacteria levels in Dr. Reed's operating theater.[22] The study was designed by Dr. Valerie Edwards-Jones, a Professor of Microbiology at Manchester Metropolitan University.[23]

According to Dr. Reed, the study showed "that there was *no difference* in contamination, *whether you use forced air warming or not*."[24] Indeed, a draft write-up of the study reported that "[t]he experiments showed *no notable increase in either ambient particle count or bacterial count in the vicinity of an operative field* when a forced air warming device was used in the normal intra-operative manner."[25] Dr. Reed did not disclose the negative findings of the microbiology study in the 2013 "crud and bug" paper on which he is lead author. That article nevertheless states the assumption—contrary to the negative microbiology results—that "*a portion of the emitted contaminants are microbial in nature*."[26]

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[20] *Id.* at 66:2–67:18.

[21] *Id.* at 26:11–27:3.

[22] *Id.* at 27:5–28:3.

[23] *Id.*; *see also* https://theconversation.com/profiles/val-edwards-jones-103722 (last visited August 25, 2017).

[24] *Id.* at 27:21–24 (emphasis added).

[25] McGovern Deposition Exhibit 10A at 3615–26 (DX 16) at 3615 (emphasis added).

[26] Reed 2013 (DX 3) at 280 (emphasis added).

Paul McGovern arrived as a trainee in Dr. Reed's orthopedic surgery department in 2009, and worked on in the microbiology study.[27] He later met Albrecht to conduct an experiment comparing the effects of the Bair Hugger and the HotDog on airflows in Dr. Reed's operating room, this time using bubbles instead of smoke.[28] According to McGovern, Albrecht "was the person who knew how to use the bubble generator. And so he used that [and] directed its use[.]"[29] McGovern, Albrecht, and Reed published the results of the "bubble" experiment in 2011 as part of their article, "Forced-air Warming and Ultra-clean Ventilation Do Not Mix."[30]

But the publication of the McGovern paper was not without setbacks. On July 18, 2010, Dr. Reed wrote to Albrecht, copying McGovern and Dr. Augustine, to express the "concern . . . that we couldn't replicate this effect in our own OR."[31] He continued:

> I wonder if you would consider setting the experiment up again and simply demonstrating the effect to Paul and I via skype. Not suggesting at all that it is repeated but that we can simply see the bubbles rising into the surgical site with this set up, and that we can see the particle counts measured so high in the surgical field. We could use that video in our blog anyway. Sound plausible? **If we are publishing/speaking on this we need to have witnessed the phenomenon if our own OR**

[27] Deposition of Dr. Paul McGovern ("McGovern Dep."), DX 17, at 18:23–20:5; 22:3–15.

[28] *Id.* at 68:21–69:4; 79:8–16; 82:8–10.

[29] *Id.* at 80:6–18.

[30] McGovern 2011 (DX 18). This is the "McGovern" paper that also compares infection rates following Reed's hospital's switch from Bair Hugger to HotDog. The infection rate comparison is the focus of Defendants' motion to exclude plaintiffs' medical experts.

[31] Augustine Deposition Exhibit 60 (DX 19).

> **didn't show that effect** (although the air bubbles did rise to some extent with us).[32]

In other words, Reed and McGovern were unable to replicate the effects of bubbles and particle counts rising without Albrecht operating the equipment. Albrecht initially agreed to conduct the Skype demonstration, but his equipment was impounded by British customs agents.[33] On August 20, Albrecht wrote back to say "I fear that our ability to get this completed manuscript in . . . will continue to be delayed for some time if we rely upon that equipment to demonstrate the effects for both of you in our laboratory."[34] He proposed to have Bob Gauthier (an old friend of Augustine's and a co-author on one of the "crud and bug" papers) and Chris Nachtsheim (Albrecht's statistics professor at the U of M) "vouch" for the results, and to have Gauthier take over as lead author.[35] But the paper was ultimately published with McGovern as the lead. The July 2010 draft's discussion of rising particle counts during Bair Hugger operation did not make the final article[36]—possibly because Reed and McGovern's microbiology experiments *had already shown* that particle counts did not rise when the Bair Hugger was switched on.[37]

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[32] *Id.*

[33] *See* Nachtsheim_0000481 (DX 20).

[34] *Id.*

[35] *See id.*

[36] *See* AUGUSTINE_0006980 (DX 21) at 0006986, 88–89.

[37] *See* McGovern Dep. Exhibit 10A (DX 16) at 3615.

C. Augustine Motivates Legg to Conduct Particle and Bubble Experiments, and Another Secret Microbiology Study Comes Back Negative.

While in England to work with Reed and McGovern, Albrecht took his "bubble kit" on the road to Sheffield, where he met with another orthopedic surgery trainee, Andrew Legg. A couple of months before Albrecht's visit, Legg had conducted a particle counting experiment using equipment provided by Augustine's UK representative.[38] Legg was motivated to conduct the experiment by the "green smoke" video on the HotDog website, which he discovered through a HotDog promotional brochure that a senior colleague, Dr. Andrew Hamer, had shared with him.[39] In that experiment, Legg had a junior doctor lie on the operating table while he took temperature measurements and counted particles during Bair Hugger and HotDog use.[40] Legg was not able to visualize the airflow in his experiment, however, so he contacted the UK HotDog representative for help.[41] The representative sent Mark Albrecht and his bubble generator.

As he had done with Reed and McGovern, Albrecht once again set up the bubble machine, temperature probe, and camera, and according to Legg, "used it to make the bubbles, and took the pictures of the bubbles[.]"[42] Albrecht later sent Legg and his adviser, Dr. Hamer, a draft article based on the results. According to Legg, he and Hamer were very displeased with Augustine and Albrecht's presumptuousness:

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[38] Deposition of Dr. Andrew Legg ("Legg Dep.") (DX 22) at 29:4–25; 35:13–18.

[39] *Id.* at 34:8–23.

[40] *Id.* at 39:5–17.

[41] *Id.* at 35:5–12.

[42] *Id.* at 32:12–33:3.

> [W]e were unhappy with how we had been managed, in terms of this paper had been pushed onto us, we had never had agreed that would be the case, and when we explained and expressed our, how unhappy we were about this, they were fairly abrupt and aggressive in their response and suggested that this was normal practice.[43]

Legg and Hamer nevertheless went on to publish two papers based on the experiments:

- Legg A., et al., "Do forced air patient-warming devices disrupt unidirectional downward airflow?" *J. Bone and Joint Surg. Br.* (2012) (DX 23), which was based on the first experiment conducted with the Augustine equipment; and
- Legg A., et al., "Forced-air patient warming blankets disrupt unidirectional airflow" *Bone and Joint J.* (2013) (DX 24), which was based on the bubble experiment conducted by Mark Albrecht.

Legg did not disclose Augustine's or Albrecht's involvement in either paper, however. But for discovery conducted in this litigation, no one else would know that Augustine instigated both publications, or that Albrecht performed the experiment that was the basis for the second one.

Legg's omission of Albrecht and Augustine's role in the experiments was not his only material non-disclosure. He also failed to mention that he had actually tried "to identify if there was any increased bacterial level" associated with the Bair Hugger.[44] In the first experiment, with the Bair Hugger on, Legg attempted to measure bacteria using a "slit sampler," which sucks air on to an agar plate.[45] He took the samples at the "surgical site," and all of them came back with less than one CFU—the same level his hospital

[43] *Id.* at 66:7–67:4.

[44] Legg Dep. (DX 22) at 53:2–21.

[45] *Id.*

required for operating room air generally.[46] Thus, just like Reed and McGovern, Legg conducted an experiment to detect an increase in *actual bacteria*—not just particles—and found nothing. Legg nevertheless went on to write in his 2012 paper that "the significant increase in the number of *particles* that we found in this study at the surgical site *is of concern*."[47] Legg conceded at his deposition that "[i]t's only a theoretical concern because I didn't prove it."[48]

D. Augustine Stops Looking for Bacteria and Returns to "Green Smoke" and Particle Counting.

The mastermind behind Albrecht's "British Invasion" was, of course, Scott Augustine. In a lengthy message to Mike Reed, who had proposed additional bacterial sampling after the negative results of his microbiology study, Augustine shared his thoughts on the path forward for negative Bair Hugger research:

> My suggestion for further research would be to start by basically replicating and thus verifying the research that we have done in our lab. Maybe not too exciting but practical and very useful.
>
> 1.) **Use tracer smoke under the table and particle counting above the table** (after-hours with a mannequin instead of a patient), both in a real laminar flow and non-laminar flow OR.
>
> 2.) In the UK laminar flow lab, **replicate the DVD with smoke and laser lights.**

[46] *Id.* at 53:25–54:4.

[47] Legg 2012 (DX 23) at 256 (emphasis added).

[48] Legg Dep. (DX 22) at 116:13–20.

> **I like this plan because we know the outcomes before we do the studies** and yet they are scientifically and clinically important questions that need verification in multiple studies.
>
> ***
>
> I personally am not too excited about culturing the wound at the end of the case, either directly or by irrigation. Without having done a pilot study, **this is a "crap shoot" that could go either way**. I think it is important to consider that even if this type of study were to turn out positive, it could be considered to simply be another intermediate step similar to particle detection over the wound. **In other words it does not conclusively answer the question of "does FAW cause wound infections?"** Therefore, **I'm not sure that it really adds enough to our case to take the risk of a negative study.**[49]

To sum up this extraordinary communication, Augustine told his top outside researcher that he would rather do more smoke and laser experiments "because we know the outcomes before we do the studies," and that he would rather *not* do any more microbiology studies in order to avoid "the risk of [another] negative study."

Based on these views, it should come as no surprise that the next study Augustine chose to pursue when Albrecht returned stateside was another bubble experiment. In early 2011, Albrecht retained a friend and former colleague of Augustine's at the University of Minnesota, Dr. Kumar Belani, to conduct an "Evaluation of Patient Warming Excess Heat on Ventilation."[50] Belani had already provided guidance to Albrecht on the "crud and bug"

[49] McGovern Deposition Exhibit 1A 445–452 (DX 25) at 456 (emphasis added).

[50] Deposition of Dr. Kumar Belani ("Belani Dep.") (DX 26), at 46:21–47:2; Belani Deposition Exhibit 11 (DX 27).

study that would be published, with Belani as a co-author, later that year.[51] But the new study would set aside the "crud and bug" issues and focus on airflow. Albrecht proposed to conduct an "[a]irflow pattern visualization via neutrally buoyant detergent bubbles."[52] Consistent with Augustine's directive, the protocol did not call for using slit samplers, agar plates, or any other means of measuring bacteria.

The University of Minnesota "bubble study" was published in August 2013 with Dr. Belani as lead author.[53] The year before, Albrecht succeeded in publishing an article based on a "temperature mapping" comparison of Bair Hugger to two conductive blankets, including HotDog.[54] The experiments had been conducted by two British researchers, Mark Harper and Kiran Dasari, in late 2010. After receiving the raw data, Albrecht told Harper and Dasari, copying Augustine, "I think there is enough data here for a full manuscript" and volunteered to write it himself.[55]

Finally, the Reed paper—the last installment of the "crud and bug" trilogy—went to press in August 2013, the same month as the publication of the Belani article. Although

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[51] Belani Dep. (DX 26) at 184:8–185:20 ("I do remember telling him to include several hospitals and pick up the Bair Huggers that are used in the hospitals at that time currently, and to look at the filters to see how they – how they – how they are actually performing, and to do the running in the operating room itself").

[52] Belani Deposition Exhibit 11 (DX 27) at 9.

[53] Belani K., et al., "Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance" *Anesth. Analg.* (2013) (DX 28).

[54] Dasari K., et al., "Effect of forced air warming on the performance of operating theatre laminar flow ventilation" 67 *Anaesthesia* 244 (2012) (DX 29).

[55] *See* Harper_0000106 (DX 30) ("I'd be willing to help you draft a full manuscript for this data if you would be open to the idea of adding me as a co-author on such a manuscript . . . .").

Albrecht completed the initial manuscript of the Reed article in the summer of 2010, the authors encountered unexpected resistance from journals. Albrecht initially told Reed to "target the top tier journal [in orthopedics] for we can make a good case as to the relevance of this data/research."[56] But in early 2011, the Journal of Bone and Joint Surgery rejected the submission.[57] Albrecht told his co-authors that he had "done quite a bit of rework on the article to make it more attractive" to the next target journal, Anesthesia & Analgesia.[58] Nevertheless, Oliver Kimberger, the co-author who had hosted the "crud and bug" tests in Vienna, recommended that Albrecht "tone the cover letter down a bit, it might actually increase the chances of acceptance . . . "[59]

Anesthesia & Analgesia also rejected the "European 'crud and bug'" manuscript, however.[60] The Editor told Albrecht, "Your conflict of interest is at the heart of this."[61] He cautioned that due to Augustine's competing device, "[y]our manuscript must be 'squeaky clean.'"[62] In addition to the conflict, the A&A reviewers noted several flaws in the paper, including the following highly perspicacious observation:

> A striking omission from this manuscript is that **exhausted air was not cultured!** This is the one outcome that might plausibly have been related to clinical infection. It is hard to

[56] *See* Gauthier Deposition Exhibit 16 (DX 31)

[57] *See* Gauthier Deposition Exhibit 20 (DX 32)

[58] *Id.*

[59] *Id.*

[60] *See* Gauthier Deposition Exhibit 22 (DX 33) at 289.

[61] *Id.*

[62] *Id.*

> believe that these measurements were not made. **Why weren't they reported?**[63]

More than likely, the "exhausted air was not cultured" from the Bair Hugger units because Augustine considered it a "'crap shoot' that could go either way." Of course, that does not excuse Albrecht, Reed, and McGovern's failure to report their negative microbiology study.

Albrecht took to heart the A&A Editor's comment about the conflict of interest, and reached out to Dr. Kimberger for "a little help 'sanitizing' [the manuscript]."[64] He asked Kimberger to "go through the attached manuscript and identify what needs to be removed to get rid of the 'agenda,'" because "[i]n its present form, I do not think it would pass review at another journal."[65] Kimberger agreed, and Albrecht notified the co-authors (including McGovern and Reed) that "I've asked Oliver to help us sanitize the manuscript. Once he is done, we can try to re-submit elsewhere."[66]

In April 2011, Albrecht tried again with the Journal of Hospital Infection. But they quickly rejected the article too, as Albrecht reported to his co-authors and Augustine:

> Well, I don't necessarily have good news to report here on our re-submission to the journal of hospital infection. **They were really quick to dismiss our "sanitized" article.** In fact, they didn't even deliberate over the issue ... even a little bit.[67]

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[63] *Id.* at 293.

[64] *Id.* at 288.

[65] *Id.*

[66] *Id.*

[67] Gauthier Exhibit 23 (DX 34) at 174 (emphasis added).

Albrecht felt that the abrupt dismissal was due to the "controversial" nature of the topic, but he overlooked important substantive comments from the reviewer, including the following:

> There is no indication that the excess measures [of] particles found after the filter have any infection transmission significance. **Their occurrence as irrelevant non-viable particles has not been excluded (and does seem the most probable explanation).**[68]

Albrecht and Augustine decided to "take one more shot at a top tier journal"—Anesthesiology.[69] Because Augustine knew the Editor-in-Chief, Albrecht suggested that "Scott make[] contact in advance of our submission to let him know it is coming in and, hopefully, this will encourage a 'fair' review of the work."[70] Albrecht confided to Kimberger that Anesthesiology "might very well reject this at first pass also, but its [*sic*] worth a shot *before we just dump this into a nursing journal* or something like that."[71] But Anesthesiology also rejected the article, and in the summer of 2013 it finally appeared in the American Association of Nurse Anesthetists Journal—a "nursing journal."[72]

Thus, by late 2013—within six years of launching the "Blowing Air is Risky" campaign—the Augustine/Albrecht "Publication Factory" had churned out three "crud and bug" papers (Albrecht 2009, Albrecht 2011, and Reed 2013) and five "airflow disruption"

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[68] *Id.* at 176 (emphasis added).

[69] *See id.* at 174.

[70] *Id.*

[71] *Id.* at 177 (emphasis added).

[72] *See* Reed 2013 (DX 3).

papers (McGovern 2011, Legg 2012, Dasari 2012, Legg 2013, and Belani 2013). These eight studies form the backbone of plaintiffs' allegations in the Master Long Form Complaint.[73]

E. Plaintiffs' Engineers Wholly Adopt Augustine's Theories.

Just as he developed the "Litigation Guide"[74] to recruit Plaintiffs' counsel and promote Bair Hugger lawsuits, Augustine's body of "research" serves as the both the source and the template for Plaintiffs' experts' opinions. Plaintiffs' engineers fully embrace the "Reservoir of Infection" and "Airflow Disruption" theories: Mr. Koenigshofer claims that the Bair Hugger's filters are inadequate, and that "[t]he hot air from the Bair Hugger will interfere with the downward flow of clean air;"[75] Mr. Buck says that "the Bair Hugger causes an increase in the number of particles in the operating room, and in particular, in close proximity to the surgical site;"[76] Dr. Elghobashi built a computer model to simulate the idea that "[t]he use of a Bair Hugger . . . disrupts the turbulent airflow

[73] *See* Plaintiffs' Master Long Form Complaint (Doc. 46-1) at ¶63(a)–(r). Plaintiffs list other publications besides the "crud and bug" and "airflow disruption" articles, but those are either reviews that contain no original research (Wood); comparisons of the effectiveness of conductive and convective warming (Brandt, Kimberger, Matsuzaki, Negishi, and Ng); a case report of contamination found on the outside of a Bair Hugger filter (Bernards); a caution not to re-use the single-use Bair Hugger blankets (Sigg); or a study that found no bacteria escaping the Bair Hugger system with the blanket connected (Avidan). The core Bair Hugger papers that Plaintiffs rely on are the eight orchestrated by Augustine and Albrecht (references 63(a–f), (l), and (p)).

[74] The background of Augustine's "Litigation Guide" is discussed in Defendants' brief in support of its Motion for Leave to Take Additional Depositions and Continue the Deposition of Dr. Scott Augustine (ECF No. 413).

[75] Expert Report of Daniel Koenigshofer ("Koenigshofer Rept.") (DX 35) at 23.

[76] Expert Report of Michael Buck ("Buck Rept.") (DX 37) at 17.

around the operating table;"[77] and Dr. David concludes based on the Albrecht, Reed, McGovern, and Legg articles that "the Bair Hugger harbors bacterial growth, interferes with operating room airflow, and introduces particles into the sterile field."[78] None of plaintiffs' engineers presents a new concept for how the Bair Hugger could cause a surgical infection, or offers experimental results that add anything to the work that Augustine's team conducted between 2009 and 2011.

The engineers' failure to advance Augustine's research agenda dooms their general causation opinions, especially in light of the FDA's recent "safety alert" on "Forced Air Thermal Regulating Systems" (of which the Bair Hugger is the most used).[79] On August 30, 2017, the FDA announced its "continu[ing] . . . recommend[ation]" to "use . . . thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted."[80] The agency explained that it had "collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements."[81] After a "thorough review" of this information—which would have included all of the "crud and bug" and "airflow disruption" papers—the FDA was "unable to identify a consistently

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[77] Expert Report of Said Elghobashi ("Elghobashi Rept."), (DX 36) at Exhibit 2 p. 2.

[78] Expert Report of Yadin David ("David Rept."), filed under seal at ECF No. 316, at 27.

[79] https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574053.h;tm (last visited September 4, 2017).

[80] *Id.*

[81] *Id.*

reported association between the use of forced air thermal regulating systems and surgical site infection."[82]

Notwithstanding the FDA's assessment that there is no consistent association between Bair Hugger use and surgical infections, Plaintiffs' engineers rely on Augustine's eight articles to draw conclusions that the authors themselves were unwilling to make. As the Court has already seen, each of the eight articles disclaims support for a causal relationship.[83] Indeed, some of the authors where especially careful to emphasize the limitations of their findings:

- "[T]he definitive effects of this excess heat on clinical outcomes is presently unknown." (Dasari 2012)[84]
- "[W]e are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery." (Belani 2012)[85]
- "[W]e are unable to confirm if any of the particles were transporting bacteria[.]" (Legg 2012)[86]
- "It does not appear that the forced-air warming device itself blows potentially contaminated warm air directly into the [laminar flow area]." (Legg 2013)[87]

Even Albrecht, McGovern, and Reed—the authors with the closest ties to Augustine—only described their theories in terms of *possibilities*:

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[82] *Id.*

[83] *See* Defendants' Memorandum in Opposition to Plaintiffs' Motion for Leave to Amend to Add Claim for Punitive Damages, ECF No. 436 at 7–8.

[84] DX 29 at 248.

[85] DX 28 at 410.

[86] DX 23 at 256.

[87] DX 24 at 409.

- "[A] significant percentage of FAW blowers with positive microbial cultures were emitting [particles] within the size range of free floating bacteria and fungi (<4 μm) that *could, conceivably*, settle on to the surgical site." (Albrecht 2009)
- "[T]his study highlights the *potential* risks of intraoperative surgical site contamination when FAW devices are used in clean OR environments." (Albrecht 2011)
- "[T]he upward mobilization of floor-level and under-drape air *could potentially* compromise the sterility of the surgical site[.]" (McGovern 2011)
- "[F]or a direct risk to be present, the exhausted FAW airflow would need to reach the surgical site. It is presently unknown whether this happens[.]" (Reed 2013)

The authors' restraint is appropriate; as one critical review noted, "We do not believe that experimental studies using machines that emit bubbles in mock surgical procedures is a proven or standardized method to assess the risk of operative site contamination."[88] But while Augustine's authors hedge their conclusions, Plaintiffs' engineers show no such reticence. Each of them expresses his opinions "to a reasonable degree of engineering *certainty*."[89]

This motion will demonstrate that Plaintiffs' engineers, while adopting Dr. Augustine's mechanistic hypotheses, have failed to elevate them above their flawed, biased, and deceitful origins. There is no basis for their expression of "certainty," only

[88] Duke Infection Control Outreach Network, "Hot Dogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods" 10 *Infection Prevention News* (2015) (DX 38).

[89] *See* Koenigshofer Rept. (DX 35) at 23; Elghobashi Rept. (DX 36) at Ex. 2 p.1; David Rept. (ECF No. 316) at 1. The exception is Mr. Buck, who does not actually have an engineering degree; he will testify instead to his "professional opinion." *See* Buck Rept. (DX 37) at 17.

more speculation about how the Bair Hugger might cause bacteria to reach the surgical site.

II. SUMMARY OF PLAINTIFFS' ENGINEERS' BACKGROUND AND OPINIONS.

Having explained the "Augustinian" roots of Plaintiffs' theories, we review Plaintiffs' engineers' backgrounds and opinions.

A. Daniel Koenigshofer.

Mr. Koenigshofer is an HVAC engineer who works with hospitals but has no experience with patient warming devices. He has not written any articles about patient warming devices and is not aware of any regulations or standards that apply to them.[90] Mr. Koenigshofer has not taken any measurements of air temperature or velocity coming out of a Bair Hugger blanket, or conducted any experiments of any kind on a Bair Hugger device.[91] The one time that he examined a Bair Hugger warming unit was during a meeting with Plaintiffs' counsel earlier this year, in which he unscrewed the upper and lower housing from each other "so I could see inside."[92] He did not actually turn the unit on, however.[93] He has never felt the flow of air from a Bair Hugger blanket, or even from the

[90] Deposition of Daniel Koenigshofer ("Koenigshofer Dep.") (DX 39) at 56:9–11, 106:24–107:4.

[91] *Id.* at 100:4–22.

[92] *Id.* at 100:23–101:6; 101:19–24.

[93] *Id.*

hose without the blanket.[94] He does not consider himself to be an expert in laminar flow.[95] Nevertheless, he opines that "[t]he hot air from the Bair Hugger will interfere with the downward flow of clean air from the ceiling diffuser."[96]

Mr. Koenigshofer's "airflow disruption" argument assumes that operating room air moves in an orderly and predictable manner from the ceiling diffusers, over the patient, and out through the return vents, and that the only device that disturbs this fragile pattern is the Bair Hugger. But an operating room during orthopedic surgery is not like a still pond on a cloudless day. The airflow over the surgical table is constantly disrupted by the surgeon and the staff. In addition, numerous studies have shown that traffic in and out of the operating room has a significant impact on airflow and airborne contamination. In one such study, the authors observed a whopping 529 door openings in just 30 surgeries, which the authors correlated to higher CFU/m^3 counts in the operating room.[97]

Moreover, Koenigshofer's argument suggests that the Bair Hugger is the only piece of operating room equipment capable of interfering with airflow, but this is belied by Dr. Augustine's survey of operating room equipment that gives off heat, moves air, or both:[98]

- Head light
- Electrocautery
- Defibrillator

[94] *Id.* at 102:4–10.

[95] *Id.* at 92:7–9.

[96] Koenigshofer Rept. (DX 35) at 23.

[97] Andersson A., et al., "Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery" 40 *Am. J. of Infection Control* 750 (2012) (DX 40) at 752–53.

[98] Augustine Deposition Exhibit 51 (DX 41).

- Heat pump
- Slush machine
- Transesophageal echo machine
- Heater/cooler (perfusion)
- Computer
- Anesthesia Machine
- Vacuum Canisters

Not all of these machines are used in orthopedic surgeries, but Augustine's list does not include drills and saws, which are essential tools for any hip or knee replacement. Orthopedic drill bits and saw blades produce significant heat while generating copious airborne debris.[99] In sum, operating room air is diverted in countless directions by the radically unpredictable movements and interactions of staff and equipment. To suggest that airflow "disruptions" can be uniquely traced to the Bair Hugger is pure folly.

Mr. Koenigshofer also opines that "[t]he filters in the Bair Hugger are less efficient that [*sic*] those used in the HVAC system serving an OR."[100] But he has never conducted any testing to determine the efficiency of an air filter used in a hospital, and he has no expertise with ASHRAE 52.2, the standard that filter manufacturers rely on to rate the efficiency of their products.[101] He agrees that ASHRAE standard 170—which he considers

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[99] *See* Bertollo N., et al., "Drilling of Bone: Practicality, Limitations and Complications Associated with Surgical Drill-Bits," http://cdn.intechweb.org/pdfs/19652.pdf (last visited August 28, 2017) at 68 ("Maximal temperatures in excess of 100˚C are not uncommon during the machining of bone with rotational cutting tools"); *see also* Toksvig-Larsen S., et al., "Temperature Influence in Different Orthopaedic Saw Blades" 7 *J. of Arthroplasty* 21 (1992) (DX 42) (measuring average saw blade cutting temperatures above 100˚C).

[100] Koenigshofer Rept. (DX 35) at 23.

[101] *See* Koenigshofer Dep. (DX 39) at 81:15–21. ASHRAE is the American Society of Heating, Refrigeration, and Air Conditioning Engineers. *See* https://www.ashrae.org/ (last visited September 8, 2017).

"the bible" for hospital HVAC design[102]—requires a "minimum efficiency reporting value" or "MERV" of 14 for operating room filters.[103] MERV 14 provides a level of filtration that ASHRAE considers appropriate for controlling "all bacteria."[104] But Koenigshofer did not review any of the test reports 3M has produced confirming that Bair Hugger filters meet MERV 14.[105] When confronted with examples of those reports, he protested that the filters were tested in a laboratory and not in a Bair Hugger warming unit.[106] This objection proved to be half-hearted:

> A. It was not in a Bair Hugger.
> Q. Right.
> A. So --
> Q. Did you ask --
> A. -- it was in a perfectly beautiful sealed-in device.
> Q. Okay.
> A. Perfectly. We've got quarter-inch stainless steel ends on this thing and wonderful perfect gaskets installed by a Ph.D technician in the laboratory.
> Q. Do you know that these people are Ph.D technicians?
> A. No, I don't know. I'm just making this shit up.
> Q. I think I understand.[107]

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[102] *See* Koenigshofer Rept. (DX 35) at 5.

[103] Koenigshofer Dep. (DX 39) at 129:10–18.

[104] *See* ASHRAE Standard 52.2-2017, Koenigshofer Deposition Exhibit 14 at 45 Table E-1 (DX 43) (specifying filters in the range of MERV 13–16 for controlling "all bacteria").

[105] Koenigshofer Dep. (DX 39) at 289:20–23. For examples of test reports confirming the Bair Hugger filters meet MERV 14, *see* Koenigshofer Deposition Exhibits 27 and 28 (DX 44).

[106] Koenigshofer Dep. (DX 39) at 291:18–292:2.

[107] *Id.* at 292:14–293:5.

Koenigshofer also opines that the Bair Hugger warming unit "functions much like a household vacuum cleaner," and that "[t]he air velocity at the floor under the Bair Hugger is sufficient to entrain particles from the floor."[108] But while Koenigshofer calculated the face velocity of the air entering the Bair Hugger, he did not determine the velocity that would be necessary to dislodge particles of the size that can carry bacteria.[109] This is significant, because as one researcher has commented, "[t]he magnitude of adhesive forces relative to the particle mass increases significantly for micrometer- and submicrometer-sized particles, and their removal is therefore difficult."[110] In other words, the smaller the particle, the more tenaciously it will adhere to a surface and resist being lifted off by air currents. This is a well-known problem in semiconductor manufacturing, where great efforts have been made to remove micron- and sub-micron-sized particles from silicon wafers.[111] Koenigshofer took none of this into account in arriving at his "household vacuum cleaner" opinion.

Koenigshofer also claims that the Bair Hugger blows "at least 300 CFU [per hour] . . . near the patient," but his "calculation" of this figure is riddled with erroneous assumptions. First, relying on a paper from 1968, he assumed a baseline level of bacteria

[108] Koenigshofer Rept. (DX 35) at 22–23.

[109] Koenigshofer Dep. (DX 39) at 308:9–12.

[110] Ranade M., "Adhesion and Removal of Fine Particles on Surfaces" 7 *Aerosol Sci. and Technol.* 161 (1987) (DX 45) at 161.

[111] *See id.* The article explains that "[a]ir or nitrogen blowoff guns are usually effective in removing large particles (> 10 μm) from the surface but ineffective in removing smaller particles." *Id.* at 173.

in air near the floor of 350 CFUs per cubic meter.[112] This would make for an extraordinarily contaminated operating room. While there are no regulations in the U.S. limiting CFU/m^3 in operating rooms, it has been suggested that levels be maintained below 10 CFU/m^3 during implant surgery.[113] Koenigshofer assumed a level 35 times greater than that. Next, Koenigshofer assumes that the Bair Hugger filter will only trap 90% of bacteria-carrying particles due to "leaks [in] the assembly," but he admits he has never leak-tested a Bair Hugger warming unit.[114] Finally, he speculates that as many as 10% of the CFUs that escape the filter will make it out of the blanket, which is contrary to published research by Avidan et al., who attempted to detect CFUs emitted from Bair Hugger blankets and found none.[115] In this manner, Koenigshofer built his "300 CFU per hour" exposure estimate entirely on false assumptions and speculation.

Koenigshofer also fails to account for the fact that even if bacteria were to find their way past the filter and out the Bair Hugger blanket, they would still have to get past the blankets, tapes, and drapes that wall off the Bair Hugger from the surgical site.[116] And even then, they would still have to travel up and over the anesthesia screen, against the downward flow of the ceiling vents, and drift all the way across the patient's upper body

[112] Koenigshofer Dep. (DX 39) at 304:6–15.

[113] Andersson 2012 (DX 40) at 750–51.

[114] Koenigshofer Dep. (DX 39) at 226:3–5.

[115] *See id.* at 240:20–243:14; *see also* Avidan 1997 (DX 64).

[116] *See* Expert Report of Michael Mont, Exhibit F (DX 46).

and torso to land in the surgical wound. Koenigshofer has not shown that this "Mission Impossible" can ever be accomplished.

Koenigshofer ultimately opines that "use of the Bair Hugger will adversely affect the air quality in the OR and at the patient. This will place the patient at increased risk of contracting [a hospital acquired infection]."[117] While he blames the Bair Hugger for "interfer[ing] with the downward flow of clean air," he recognizes that a hospital's HVAC system can only do so much to prevent infections. He once wrote that "[y]ou can put the cleanest air in the world in the room, but if skin particles are falling off the doctors and nurses into the surgical site, that's a problem that can't be solved by the HVAC system."[118] Needless to say, this problem exists regardless of whether a Bair Hugger is in the room.[119]

Finally, Koenighofer's opinions presume that the predominant source of pathogenic bacteria is operating room air, but that is not the case. As Plaintiffs' infectious disease expert William Jarvis wrote for the CDC in 1999, "For most SSIs, the source of pathogens is the *endogenous flora* of the patient's skin, mucous membranes, or hollow viscera."[120] As Koenigshofer himself notes in his report, "most experts agree that airborne sources of infection are responsible for 5-15% of [hospital acquired infections]."[121] Thus, while

[117] Koenigshofer Rept. (DX 35) at 23.

[118] Koenigshofer Deposition Exhibit 10 (DX 48) at 9.

[119] Koenigshofer Dep. (DX 39) at 312:14–25.

[120] Guideline for Prevention of Surgical Site Infection, 1999, Centers for Disease Control and Prevention (Jarvis Deposition Exhibit 5) (DX 47) at 103.

[121] Koenigshofer Rept. (DX 35) at 6.

airborne bacteria should not be ignored as a potential source, they are simply not a significant contributor to surgical infections.

B. Michael Buck.

Mr. Buck is an Environmental Health and Safety Compliance Specialist at the University of Minnesota.[122] His early professional experience involved asbestos identification and abatement; he transitioned to indoor air quality investigations in approximately 1999.[123] Most of his indoor air quality work has involved water-damaged buildings, although he has also conducted routine environmental checks at the University's Fairview Riverside Hospital.[124] He claims no expertise in microbiology, filtration, heat transfer, or the prevention of surgical site infections.[125] Before his retention in this case, he had no experience with patient warming devices.[126] He also manages the Microbiology Lab for the University's Department of Environmental Health and Safety, but he took no microbiological samples in his experiments for this case.[127]

In his report, Mr. Buck says he "was retained to evaluate whether or not the Bair Hugger Forced Air Warming System generates and/or omits [*sic*] particles."[128] Plaintiffs

[122] Buck Rept. (DX 37) at 3.

[123] Deposition of Michael Buck ("Buck Dep.") (DX 49) at 39:13–40:2; 40:10–17.

[124] *Id.*

[125] *Id.* at 36:6–39:5.

[126] *Id.* at 39:6–12.

[127] Buck Rept. (DX 37) at 3; Buck Dep. (DX 49) at 87:4–6.

[128] Buck Rept. (DX 37) at 4. In his deposition, Mr. Buck agreed with Plaintiffs' counsel's clarification that he meant "emits." Buck Dep. (DX 49) at 88:2–15.

did not ask him to test their "Reservoir of Infection" theory to see whether the Bair Hugger releases bacteria.[129] Instead, they asked him to measure emissions of *particles* from the Bair Hugger hose and blanket. Buck tested two Bair Hugger warming units "to determine the number and size of any particles generated by the unit itself through normal operating procedures."[130]

In Buck's first experiment, he counted thousands of particles in the range of 0.3-0.5 microns (µm) exiting the Bair Hugger hose.[131] By comparison, he found few, if any, particles larger than 5µm, and even fewer over 10µm.[132] In the second experiment, he again counted thousands of tiny particles and very few larger than 2µm.[133] Finally, for his third experiment, Buck counted particles emitted from a Bair Hugger blanket enclosed in a plastic storage bin:[134]

[129] Buck Dep. (DX 49) at 87:4–6 ("Q. Were you asked to do an evaluation of bacteria counting as part of your testing? A. No.").

[130] Buck Rept. (DX 37) at 7.

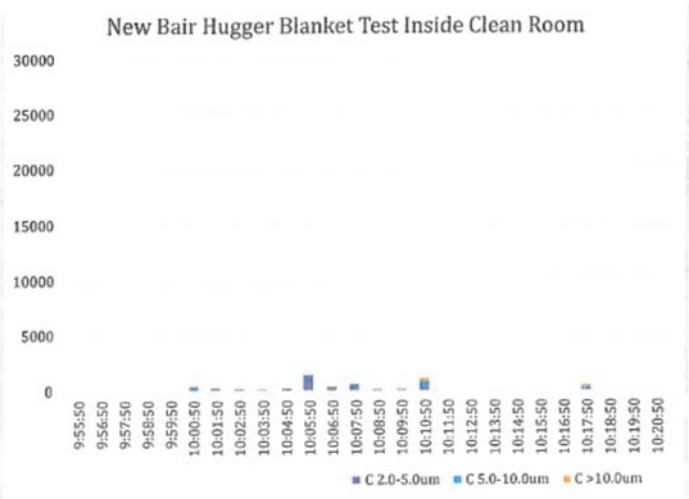
[131] *Id.* at 8–10. Buck did not attempt to characterize these sub-micron particles. Buck Dep. (DX 49) at 90:12–19. He did say, however, that "I think there's internal particles that could be generated as a result of the electrical components of the system." *Id.* at 89:23–25.

[132] *See* Buck Deposition Exhibit 4A (DX50). Buck's tabulated raw data show several "zero" entries for the 5µm and 10µm size ranges, while still registering thousands of sub-micron particles. *See id.*

[133] Buck Rept. (DX 37) at 11.

[134] *Id.* at 14.

This experiment again counted thousands of tiny particles and very few larger than 2µm. In fact, with the particles smaller than 2µm removed, the results were trivial:[135]



Buck acknowledged that the small number of larger particles he counted could have been introduced when he and his partner manipulated the blanket into the storage bin with their bare hands.[136]

Buck concludes that "the Bair Hugger causes an increase in the number of particles

[135] Buck Deposition Exhibit 10 (DX 51). Buck agreed that this accurately reflected his results. Buck Dep. (DX 49) at 200:20–21 ("Based on what you said, it looks correct").

[136] *Id.* at 175:3–5;177:25–178:17.

in the operating room, and in particular, in close proximity to the surgical site."[137] He acknowledges, however, that none of his experiments attempted to simulate an actual "surgical site."[138]

Like Dr. Augustine and his cohorts, Plaintiffs conflate "particles" with bacteria, and would invite the Court and the jury—relying on Buck's experiments—to assume that increases in particles directly correlate with increases in bacteria.[139] But as Plaintiffs' counsel elicited from Dr. Legg at his deposition, this is not a safe assumption.[140]

There are innumerable airborne particles, and most are too small to carry bacteria. Bacteria occupy a narrow size range from 0.5 to 1.5µm; *Staph. aureus* (including MRSA and MSSA) have a diameter of 0.9 to 1µm.[141] Moreover, bacteria tend not to travel in air as individual organisms, but rather form clumps or become attached to larger particles, such as shed epidermal skin cells.[142] According to published literature, these bacterial

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[137] Buck Rept. (DX 37) at 17. Neither of Buck's experiments attempted to simulate a mock surgery or to count particles near a hypothetical surgical site.

[138] *See* Buck Dep. (DX 49) at 201:10–17.

[139] For example, they cite Dr. Legg's finding of an increased particle count over the mock surgical site with the Bair Hugger turned on. *See* Elghobashi Rept. (DX 36) at 4, Koenigshofer Rept. (DX 35) at 17, and David Rept. (ECF No. 316) at 29.

[140] Legg Dep. (DX 22) at 101:23–102:2 ("Q. And you would agree that a particle count is not necessarily the same as an increased bacteria count? A. That's correct").

[141] *See* Buck Rept. (DX 37) at 6 (Fig. 2); *see also* Kowalski W., et al., "Airborne Respiratory Diseases and Mechanical Systems for Control of Microbes" 34 *Heating/Piping/Air Conditioning* (1998) (DX 52) at Fig. 1, Table 1.

[142] Jensen P., et al., "Sampling and Characterization of Bioaerosols" https://www.cdc.gov/niosh/docs/2003-154/pdfs/chapter-j.pdf (last visited August 27, 2017) at 89 ("Often … the bioaerosols will be clumps of microorganisms or microorganisms attached to another particle such as a skin scale or piece of lint").

clusters and bacteria-carrying particles range from 4µm to 20µm.[143] Thus, particles smaller than 1µm will generally not be bacteria, nor will they be carrying bacteria. As a result, the tens of thousands of sub-micron particles counted in Mr. Buck's experiments are *simply irrelevant.*

Moreover, the scientific literature has not shown a consistent and reliable correlation between levels of airborne particles and CFUs of bacteria—much less infection risk. Researchers have long sought to establish such a correlation in order to substitute particle counts, which are relatively quick and easy to obtain, for microbiology sampling with agar plates, which takes longer and requires laboratory analysis.[144] In one such study, researchers compared particle counts with air microbiological sampling in four empty operating rooms over a three-month period.[145] The authors found that "[m]any high values of particle counts were not associated with an increase in air microbial counts," and concluded that "there is no reason to replace microbiological sampling with particle counting for routine evaluation of microbiological contamination[.]"[146]

In a later study, Stocks et al. attempted to correlate particle counts with bacteria during orthopedic surgeries.[147] Stocks measured particles in the same ranges that Buck

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[143] Buck Dep. (DX 49) at 67:10–17.

[144] *See* Landrin A., et al., "Monitoring air sampling in operating theatres: can particle counting replace microbiological sampling?" 61 *J. of Hosp. Infection* 27 (2005) (DX 53).

[145] *Id.*

[146] *Id.*

[147] Stocks G., et al., "Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery" *Am. J. of Infection Control* 199 (2010) (DX 54).

used, and he found a correlation with CFUs—but only for particles greater than 10µm.[148] As noted, Buck's experiments counted very few particles greater than 10µm. Stocks emphasized that tiny particles should be ignored when assessing airborne bioburden: "[s]maller particles are present in much higher numbers than larger ones, so monitoring particles without discriminating for size ranges obscures identification of the larger particles that may be carrying microbes."[149]

Stocks conceded that "[t]he precision of predicting CFU/m^3 counts from particulate count was limited," and recommended that "[f]urther studies" be undertaken "to validate the use of particulate density to predict the density of airborne microbes."[150] But subsequent research has not provided the validation that Stocks hoped for. In 2012, Cristina et al. published a study of particle counts and microbiological sampling in 95 total hip or knee implant surgeries, which found no correlation between particle counts and airborne bacteria.[151] Then, in 2015, Birgand et al. published a multicenter study that compared microbiology samples, particle counts, and swabs taken from surgical wounds

[148] *Id.* at 202 ("The number of 10-µm particles/m^3 and the number of surgical staff in the operating room were associated with the CFU/m^3 at the surgical site during hip and knee joint arthroplasty").

[149] *Id.* at 203.

[150] *Id.* at 202–03.

[151] Cristina M., et al., "Can Particulate Air Sampling Predict microbial Load in Operating Theatres for Arthroplasty?" 7 *PLOSone* e52809 (2012) (DX 55). The authors reported that "The results did not reveal any statistically significant correlation between microbial loads and particle counts for either of the particle diameters considered (≥0.5µm and ≥ 5µm)."

before closure.[152] Birgand reported a "strong correlation" between particle counts and airborne CFUs, but *no association* between either of those measures and bacteria found in the surgical wounds.[153] In other words, whatever the researchers were detecting in the air, it did not correlate with bacteria in the surgical site.

In sum, Plaintiffs' attempt to conflate "particles" with bacteria is belied by the science. Most particles are *not* bacteria, and current research does not support a consistent, reliable correlation between particle counts and bacteria. As a result, it is impossible to infer that *any* bacteria were present among the particles that Buck measured in his experiments. This leaves a gaping hole in plaintiffs' "Reservoir of Infection" theory, and only highlights their decision not to look for bacteria in the air exiting the Bair Hugger hose and blanket.

C. Said Elghobashi.

Dr. Elghobashi is a Distinguished Professor of Mechanical and Aerospace Engineering at the University of California, Irvine, and a recognized expert in computational fluid dynamics (CFD). After he was retained by Plaintiffs, Dr. Elghobashi retained another CFD expert, Dr. Sourabh Apte, to build a computer simulation of the Bair Hugger's purported effect on shed skin cells ("squames") in an operating room based on inputs that Dr. Elghobashi provided.[154] Dr. Apte used his own software code to run the

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[152] Birgand G., et al., "Air contamination for predicting wound contamination in clean surgery: A large multicenter study" 43 *Am. J. of Infection Control* 516 (2015) (DX 56).

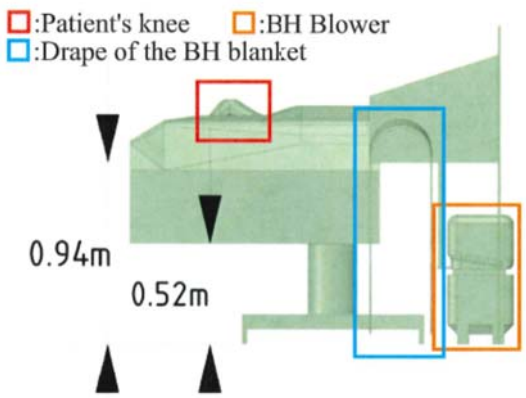
[153] *Id.* at 5 ("Air contamination was not significantly associated with wound contamination").

[154] Deposition of Dr. Said Elghobashi ("Elghobashi Dep.") (DX 57) at 55:4–56:6.

calculations and build the model.[155] Dr. Elghobashi charged Plaintiffs a total of $120,000 for Dr. Apte's CFD model.[156]

Dr. Elghobashi claims that Dr. Apte's software code has been validated by "maybe 15 papers . . . over 15 years,"[157] but one of those papers shows up to a 5 times error rate when comparing the computer model to experimental results.[158] The most glaring errors in the computer model, however, stem from Dr. Elghobashi's inputs, which he refers to as "boundary conditions."

One of the most important boundary conditions is the temperature of the air exiting the drape over the Bair Hugger blanket, which Dr. Elghobashi depicts in the blue rectangle below:



[155] *Id.*

[156] *Id.* at 127:8–10.

[157] *Id.* at 131:17–22.

[158] *See* Apte S., et al., *Stochastic modeling of atomizing spray in a complex swirl injector using large eddy simulation*, 32 *Proceedings of the Combustion Institute* 2257 (2009) (DX 58). Figure 5(a) on page 2264 shows that the computer model predicted a droplet-mass distribution as much as five times greater than the experimental results. Dr. Elghobashi references this paper among those that have "thoroughly validated" Dr. Apte's code on page 11 of his report.

The temperature and velocity of the air leaving the draped area largely determines the magnitude of the convection currents calculated by the computer model. If those values are overstated, then so will levels of the turbulence shown in the model.

Dr. Elghobashi states that "the temperature of the air leaving the drape edge is set equal to 106°F (41.11°C)," which he based on information from a 3M video.[159] But all that the video says is "[t]he air emerging from the Bair Hugger system is 106 degrees Fahrenheit"—it does not provide any specifics concerning the temperature at the drape edge.[160] He also referred to a 3M document that recorded average blanket temperatures, but Dr. Elghobashi agreed that there is no indication the temperatures listed there would reflect the temperature of the air exiting the edge of a drape over the patient and Bair Hugger blanket.[161] Thus, Dr. Elghobashi simply assumed, *without taking any measurements*, that the air leaving the edge of the drape over the Bair Hugger blanket would remain at 106°F across the *entire drape boundary*, as shown in the diagram above.[162] In other words, he assumed that the warm air exiting the Bair Hugger blanket would travel down the drape *all the way to the floor* without losing any of its heat or mixing with the cooler air in the room. Dr. Elghobashi never attempted to show that this fanciful scenario can occur in the real world.

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[159] Elghobashi Rept. (DX 36) at 32.

[160] https://www.youtube.com/watch?v=QhzeInWlJ54 (last visited August 31, 2017) at 3:59.

[161] Elghobashi Dep. (DX 57) at 67:11–69:6.

[162] *Id.* at 69:15–23.

Before he formulated his boundary conditions, Dr. Elghobashi visited a Santa Monica operating room that had been set up with a volunteer prepped and draped for a knee surgery.[163] He measured the size of the drape over the Bair Hugger, but not the temperature or velocity of the air exiting it—for that purpose, he simply ran his hand under it.[164] Ultimately, Dr. Elghobashi's determination of the air temperature at the edge of the drape was based on the YouTube video, the 3M document, "and a lot of thinking."[165] He believed it *was* necessary to measure the actual temperature of the air exiting the drape, but he lacked the equipment to do it, so he "substituted by thinking hard."[166] When asked what went into his "thought process," he responded "I can't answer that . . . It's a complex system."[167] Not surprisingly, Dr. David, who took actual measurements of the temperature of the air exiting a Bair Hugger blanket, could not replicate Dr. Elghobashi's assumption of 106°F (41.11°C)—after measuring several areas of the blanket, the highest average temperature David recorded was 36°C.[168]

The computer model purports to show that the Bair Hugger generates extreme turbulence in the operating room, much like Doppler radar tracking a line of thunderstorms. But Dr. Elghobashi made no attempt to validate the model with experimental evidence. In his opinion, "[v]alidation is needed only if you have a new code you never used

[163] *Id.* at 47:22–48:3; 71:16–72:6.

[164] *Id.* at 74:25–75:6; 76:15–77:6.

[165] *Id.* at 112:14–113:2.

[166] *Id.* at 114:4–115:8.

[167] *Id.* at 116:5–11.

[168] David Rept. (ECF No. 16) at 15.

before[.]"[169] According to NASA and the American Institute of Aeronautics and Astronautics, however, validation is "[t]he process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model."[170] Thus, without experimental validation, one cannot assume that "the conceptual models, computational models as implemented into the CFD code, and computational simulation agree with real world observations."[171] Because Dr. Elghobashi conducted no validation experiment, there is no reason to believe that what appears in Dr. Apte's computer model actually happens in real-world operating rooms.

Dr. Elghobashi relies on his "thinking" and the computer model to opine that "[t]he Bair Hugger patient warming system significantly increases the number of contaminants reaching the operating table."[172] This opinion conflicts with research by another well-known CFD researcher, Dr. Farhad Memarzadeh, who also modeled particle dispersion with a Bair Hugger in an operating room.[173] In Dr. Memarzadeh's model, funded by the National Institutes of Health, "[t]he squame plots show that particles are *cleaned away from the patient* by the airflow from the laminar diffuser *no matter if the forced air warmer*

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[169] Elghobashi Dep. (DX 57) at 127:19–20.

[170] https://www.grc.nasa.gov/www/wind/valid/tutorial/valassess.html (last visited August 31, 2017).

[171] *Id.*

[172] Elghobashi Rept. (DX 57) at Exhibit 2, p. 2.

[173] Memarzadeh F., "Active warming systems to maintain perioperative normothermia in hip replacement surgery" 75 *J. of Hosp. Infection* 332 (2010) (DX 59).

is on or off."[174] Nowhere in his report does Dr. Elghobashi address the stark differences between his general causation opinions and Dr. Memarzadeh's findings.

D. Yadin David.

Dr. David is a biomedical engineer with no medical training or background.[175] He seeks to opine on the clinical risks of using the Bair Hugger system, but he concedes that he is not a clinician, and that he does not assess clinical benefit or risk on his own; rather, he relies upon medical doctors and nurses to make those assessments.[176] Nevertheless, he offers the opinion that "the device more likely than not contributes to infections during its use in orthopedic implant surgeries" based on the "airflow disruption" and "reservoir of infection" theories:

- "First, the Bair Hugger would pose an infection risk if it disrupted or interfered with the ventilation system used in the clean environment of an orthopedic operating theater."[177]
- "Secondly, the Bair Hugger system could also pose a risk if the devices were harboring and incubating colonies of pathogenic bacteria and introducing that bacteria into the operating room air currents."[178]

Dr. David conducted no testing to assess the validity of either of Augustine's theories. He took apart a used Bair Hugger warming unit purchased through eBay; he measured the temperature of the air leaving a Bair Hugger upper body blanket (which,

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[174] *Id.* at 332 (emphasis added).

[175] David Rept. (ECF No. 16) at 3; Deposition of Yadin David ("David Dep.") (DX 60) at 247:13–16.

[176] David Dep. (DX 60) at 306:20–307:1; 307:3–9; 309:3–7.

[177] David Rept. (ECF No. 16) at 8.

[178] *Id.*

again, showed values significantly lower than what Dr. Elghobashi arrived at by his "thinking"); and he cut up pieces of paper to see whether the unit's intake velocity was sufficient to suck them up.[179] None of these activities yielded any data to support the notion that the Bair Hugger system "disrupt[s] or interfere[s] with the ventilation system . . . of an orthopedic operating theater," or that the warming unit "harbor[s] and incubat[es] colonies of pathogenic bacteria."[180] Instead, David's opinions appear to rest on his review of 13 articles—including all eight of the Augustine papers.[181]

Dr. David agrees that he did not conduct a "systematic literature review."[182] Had he done so, he would have found a long line of published studies finding *no meaningful increase in airborne bacteria* during Bair Hugger use, including the following studies published between 1991 and 2013:

Author/Reference	**Key Design Points**	**Outcome**
A.C. Hall et al. Poster Dec 9, 1991 Postgrad. Assembly in *Anesthesia* (PGA) NY, NY (DX 61)	20 patients undergoing maxillofacial surgery randomized to Bair Hugger (BH) or no BH; culture plates placed in OR.	"No detectable differences in contamination rates between groups."
R.S. Zink et al. *Anesthesia & Analgesia* 1993;76: 50-53 (DX 62)	8 volunteers on an OR table Agar plates placed on abdomen for 4 hours:	"No significant difference in the total number of bacterial colonies isolated on culture

[179] *Id.* at 10–16.

[180] *Id.* at 8, 12.

[181] *Id.* at 27 ("These studies support the conclusion that the Bair Hugger harbors bacterial growth, interferes with operating room airflow, and introduces particles into the sterile field").

[182] Deposition of Yadin David ("David Dep.") (DX __) at 267:22–268:2l; 271:16–22.

	2 hours with BH and 2 hours with control.	plates was observed between the two study periods."
W.E. Dirkes et al. *Anesthesiol.* 1994 81: No. 3A (Sept.) (DX 63)	An agar plate of β-streptococci placed 10" from filter inlet; 2 Warm Air and 1 BH device used. Air samples were cultured to measure transmission of bacteria through the devices.	"There was no transmission of beta hemolytic streptococcus by the convective warming units in any of the groups."
M.S. Avidan et al. *Anesthesia* 1997; 52: 1073-6 (DX 64)	Experiment in an empty OR with convection warmers including 9 BH units; examine growth on agar plates from sampling air from hose and blanket	4 out of 10 warming units showed growth on agar plates when placed in the air steam 16" below the end of the hose. No growth occurred when warmers were connected to blankets.
N. Tumia et al. *J. Hosp. Infect.* 2002; 52: 171–4 (DX 65)	Air samples in 2 empty theatres and during 4 orthopedic operations (3 total hip arthroplasties and 1 shoulder operation).	"This study showed that use of warm air convection heaters on patients produced a small increase in the number of colony forming units in ultra-clean air theatres but the levels were unlikely to have clinical significance. By far the greatest effect on numbers was movement and presence of the patient and theatre staff in the theatre."
J.K. Huang et al. *Crit. Care* 2003; 7.3: R 13 (DX 66)	Air samples and wound specimens during 16 vascular surgery procedures using BH.	"The results showed not only that there was no increase in bacterial counts at the study sites, but also that there was a decrease ($P<0.01$) in air bacterial content around the patient and in the operating theatre

		after prolonged use of the patient warmer."
B. Moretti et al *J. Hosp. Infect.* 2009; 73: 58-63 (DX 67)	Air samples taken during 30 THA with or without BH; 3 different sampling sites; CFU per M^3counted.	"Statistical analysis of the results demonstrated that the Bair Hugger system does not pose a real risk for nosocomial infections, whereas it does offer the advantage of preventing the potentially very severe consequences of hypothermia during major orthopaedic surgery."
L. Occhipinti et al. *Canad. Vet. J.* 2013; 54: 1157-9 (DX 68)	Randomized study involving 100 canine surgeries with/without BH; bacteria on surgical drapes counted before and after surgery.	"There was no significant difference in the number of contaminated surgical drapes between the Bair Hugger and control groups ($P = 0.47$)."

Recent research continues to show no association between Bair Hugger use and increases in airborne bacteria. In an article published earlier this year, Oguz et al. compared airborne bacterial sampling results between Bair Hugger and HotDog during eighty orthopedic surgeries.[183] The authors reported that "it was not possible to detect any higher bacterial counts on any plate in the forced air warming [Bair Hugger] group versus the resistive warming [HotDog] group."[184] Likewise, a 2017 publication by Richard et al. evaluated bacteria on 13 different surfaces within an operating room, including the interior

[183] Oguz R., et al., "Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial" 38 *J. of Clinical Anesthesia* 38 (2017) 160 (DX 69).

[184] *Id.* at 163. The authors further remarked that "with class action [*sic*] lawsuits 'judging' the scientific question of forced air safety with unsuitable, i.e. legal, means subsequent studies are all the more warranted." *Id.*

of a Bair Hugger hose.[185] The study showed that the hose interior had among the lowest levels of bacteria of any non-sterile surfaces.[186] This observation adds further support to the growing body of research showing that the Bair Hugger system does not increase airborne bacteria in operating rooms. Somehow, Dr. David missed *all* of this research, and focused instead on the Augustine studies.

Finally, just like Dr. Augustine, Dr. David misquotes the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) for the proposition that "[n]othing that blows air should be in an operating theater, if possible."[187] This ill-conceived comment by an individual CDC employee, Dr. Michael Bell, would require the removal of any surgical equipment that incorporates a cooling fan, not to mention the surgical staff and patient, all of whom "blow air." Moreover, Dr. Bell made his comment in the context of the CDC's investigation of heater-cooler units, which have the potential to aerosolize bacteria growing in the devices' water tanks.[188] Forced-air warming devices, which have no "air/water interface," do not raise the same concern.[189]

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[185] Richard R., et al., "What Orthopaedic Operating Room Surfaces Are Contaminated With Bioburden? A Study Using the ATP Bioluminescence Assay" 475 *Clinical Orthopedics and Related Res.* 1819 (2017) (DX 70).

[186] *Id.* at 1823. The authors noted that "[i]t was somewhat surprising that although the inside of the Bair Hugger™ hose does not routinely get cleaned at our institution, the degree of bioburden was relatively small compared with other OR surfaces." *Id.*

[187] David Rept. (ECF No. 316) at 43, *see* also Draft CDC/HICPAC Meeting Minutes, November 5–6, 2015 (https://www.cdc.gov/hicpac/pdf/archive/2015-november-hicpac-meeting.pdf) (last visited September 4, 2017) at 27.

[188] *See id.*

[189] *See* Deposition of William Jarvis ("Jarvis Dep.") (DX 71) at 264:14–274:22. Dr. Jarvis attempted to salvage his argument by suggesting that the CDC's use of the term "air/water

LEGAL ARGUMENT

Plaintiffs' engineers' testimony and opinions, rooted as they are in Dr. Augustine's anti-Bair Hugger crusade, cannot meet the standards of relevance and reliability imposed by *Daubert* and Rule 702. Moreover, their opinions cannot supply the "scientifically *convincing* evidence" that Plaintiffs need to "demonstrate[] to an acceptable degree of *medical certainty*" that the Bair Hugger can cause surgical infections. *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (emphasis added). Plaintiffs' engineers, who lack medical expertise, cannot carry this burden. Thus, even assuming their testimony were both relevant and reliable, it would not suffice to establish general causation.

Moreover, as *Glastetter* makes clear, it is not enough for the engineers to offer a superficially plausible mechanism by which the Bair Hugger *might* increase infection risk. They must show that it *does* increase infection risk. As Judge Cynthia Rufe recently held in the Zoloft MDL, mere "biological plausibility" will not suffice to establish general causation:

> Without admissible expert testimony based on the epidemiological evidence, Plaintiffs instead have cobbled together evidence of biological plausibility, specific causation opinions based on an assumption that general causation has been established, and anecdotal evidence. Taken together,

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interface" actually intended to communicate "air OR water interface." *See id.* at 272:3–4 ("Well, I think it means it could be air and water or and/or water."). Defendants' expert Richard Wenzel also called Dr. Bell's superior, Dr. Denise Cardo, to ask whether the CDC meant for Dr. Bell's comment to apply to patient warming devices. *See* Deposition of Richard Wenzel ("Wenzel Dep.") (DX 72) at 341:1–22. Dr. Cardo assured him that "this wasn't pertaining to forced-air warming . . . their big concern was when, you know, the heater-cooler unit was identified as a really source of serious infection." *Id.* at 272:17–20.

> Plaintiffs' potentially admissible evidence supports no more than an association between Zoloft and certain birth defects … *Causation must be based upon more than a possibility.*

In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig., 176 F. Supp. 3d 483, 498–99 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) (emphasis added); *see also Henricksen v. ConocoPhillips Co.*, 605 F.Supp.2d 1142, 1176 (2009) ("Plaintiffs' experts can only reliably attest to gasoline exposure as a theoretical or possible cause, not a probable cause of Henricksen's AML."); *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007) ("While Dr. Fogel's biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation."). Plaintiffs' engineers have not shown that the Bair Hugger system actually causes infections—or even that it causes bacteria to reach the surgical site. Their opinions and testimony must therefore be excluded.

II. PLAINTIFFS' THEORIES MUST BE EXCLUDED BECAUSE THEIR ENGINEERS DID NOT TEST THEM.

As noted at the outset, none of Plaintiffs' engineers tested the real question begged by their opinions and testimony: *Does the Bair Hugger send bacteria to the surgical site?* Augustine and Albrecht's years of negative research only managed to show emissions of irrelevant sub-micron particles, never *bacteria*. They tracked the flight paths of helium bubbles, but never showed increases in *bacteria* at the surgical site. To the contrary, their secret, unpublished work found *no bacteria* in the Bair Hugger airstream, and *no increased bacteria* at the surgical site. Rather than answer the obvious question, and attempt to

succeed where Augustine and Albrecht failed, Plaintiffs took the same conservative approach that Augustine adopted after his failed efforts to find bacteria: avoid "the risk of a negative [microbiology] study," and do an experiment in which "we know the outcome[] before we do the stud[y]." This approach "turns scientific analysis on its head:" rather than test the question at the heart of the case, "the experts here reasoned from an end result in order to hypothesize what needed to be known but what was not." *Sorensen By & Through Dunbar v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994).

From Plaintiffs' standpoint, Buck's particle experiment was a sure bet: they knew from the "crud and bug" studies that the Bair Hugger emits large numbers of sub-micron particles, so the risk of a "negative study" was minimal. And, just as expected, the Buck experiment counted thousands of sub-micron particles in the airstream of the hose and blanket. But while the Buck experiment delivered on Plaintiffs' expectations, it failed to bridge the analytical gap that the Anesthesia & Analgesia reviewer identified in the Reed (2013) paper:

> A striking omission from this manuscript is that **exhausted air was not cultured!** This is the one outcome that might plausibly have been related to clinical infection. It is hard to believe that these measurements were not made. **Why weren't they reported?**[190]

It would have been easy for Mr. Buck to lay out agar plates while running his experiments, and send them to his microbiology lab to see whether any bacteria were among the particles counted. But he did not, and Plaintiffs did not ask anyone else to search

[190] Gauthier Deposition Exhibit 22 (DX 33) at 293.

for bacteria in the Bair Hugger system.[191] Likewise, Dr. Apte's CFD computer model was not the result of a scientific experiment, but rather a "thought experiment": Dr. Elghobashi simply assumed that air would exit the bottom of the drape at the same temperature that it left the blanket, without taking measurements or pursuing experiments to determine whether the model reflects what actually happens in the real world. In this manner, Plaintiffs shied away from even attempting to advance Augustine's research—which, by itself, falls woefully short of validating their theories.

These circumstances bear a striking resemblance to those of a 2012 decision by Judge Kyle. In *Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051 (D. Minn. 2012), a newborn infant was badly burned when a fire erupted in his hospital bassinet. The plaintiffs, including the hospital, summoned well-credentialed experts who examined the forensic evidence and conducted several experiments on exemplar equipment to try to determine the fire's cause. *Id.* at 1055. They prepared a 296-page report detailing how they arrived at their hypothesis that a hot piece of quartz had broken off the heating element of a warming device, fallen into the bassinet, and started the fire. *Id.* at 1055-56. The plaintiffs' experts also relied on a "mathematical model," similar to Dr. Apte's CFD, "to calculate the temperature of quartz particles after falling from the warmer head into the bassinet." *Id.* at 1056. Critically, however, "the record contain[ed] no indication of testing to support the opinion that a large fragment broke from the quartz tube and somehow reached the

[191] If they made such an attempt, it (like Augustine, Albrecht, Reed, and McGovern's microbiology experiments) was not disclosed.

bassinet." *Id.* at 1061. The Court found the experts' decision not to test their ultimate causation hypothesis puzzling:

> Here, Plaintiffs' experts **never attempted to validate their theory** by testing how a large chip could break from the quartz tube, escape the end cap and end cover, and land in the bassinet; **they simply theorized that this might have happened**. It is undisputed that exemplar warmers were available to them and that such testing could have been performed. And perhaps most importantly, the absence of physical tests stands in stark contrast to the extensive testing the team *did* undertake with regard to *other* potential causes for the fire.

Id. at 1063 (bold emphasis added). The Court concluded that "the team's failure to physically test its hypothesis undermines the reliability of its opinion and renders it too speculative to admit." *Id.*; *see also Solheim Farms, Inc. v. CNH Am., LLC*, 503 F. Supp. 2d 1146, 1150 (D. Minn. 2007) (excluding expert's testimony because he "failed to perform any tests to verify his causation theory"); *Am. Family Ins. Grp. v. JVC Ams. Corp.*, 2001 WL 1618454, at *4 (D. Minn. 2001) (excluding expert's causation opinion because, "although an exemplar of the [device] was provided for his use, [the expert] failed to perform any testing specific to his theory").

The Court was also unpersuaded by the plaintiffs' experts' "so-called 'cognitive testing.'" *Id.* Much as Dr. Elghobashi has done in this case, the plaintiffs' experts performed a "thought experiment" instead of conducting physical tests on their theory. *Id.* The Court expressed the view that experimental validation was "particularly important" under the circumstances, because there had been no reported fires since the design of the device was changed several years earlier. *Id.* at 1064. In any event, the experts' "cognitive

testing"—their mathematical calculations of the temperature and size of the quartz particle, and the amount of energy necessary to achieve ignition—fell short of the mark:

> The calculations . . . showed only that the hypothesized quartz particle would contain enough thermal energy to ignite the bassinet's materials; **they did *nothing* to show how a particle could have broken off the quartz tube in the first place or travel from the heating element to the bassinet**. The heat-transfer calculations simply fail to bridge the analytical gap between the experts' speculation and their ultimate conclusion.

Id. at 1064 (quotes, citations, and footnote omitted) (bold emphasis added).

Here, as in the *Werth* case, Plaintiffs' engineers had ready access to Bair Hugger warming units and blankets, but they never tested their "Reservoir of Infection" and "Airflow Disruption" theories to see whether either hypothesis would deliver bacteria to the surgical site. Their choice not to pursue these tests "stands in stark contrast to the extensive testing the team did undertake" in the form of Buck's experiment and Apte's $120,000 computer model. Finally, Dr. Apte's model and the "thought experiment" on which it is based "simply fail[s] to bridge the analytical gap" between the engineers' speculation that the Bair Hugger system might send bacteria to the surgical site, and their opinion that it does. Thus, Plaintiffs' causation theories, and the testimony and opinions of their engineers in support of them, must be excluded as speculative, unreliable, unhelpful, and unsupported by experimental evidence or validation.

III. PLAINTIFFS' ENGINEERS' TESTIMONY MUST ALSO BE EXCLUDED FOR INDIVIDUAL REASONS.

A. Mr. Koenigshofer's Testimony Must Be Excluded for Lack of Expertise and an Insufficient Factual Foundation.

Mr. Koenigshofer lacks the expertise necessary to render the opinions he seeks to offer. Experts must have the necessary expertise to speak to the issues addressed by their proposed testimony. *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001). As Koenigshofer acknowledges, he is not an expert in laminar flow, and has never tested the efficiency of a filter. He does not know what level of efficiency ASHRAE considers appropriate to control "all bacteria." He has never participated in an investigation of an infectious outbreak or cluster of infections at a hospital.[192] He went so far as to say "I'm not a Bair Hugger expert" when asked about the basis for the flow rate listed in his report.[193] Koenigshofer's general background as an HVAC engineer simply does not qualify him to opine that the Bair Hugger "will place the patient at increased risk of contracting a [hospital acquired infection]."

Moreover, to the extent that Koenigshofer supports his opinions by "making [things] up," they must be excluded for that reason as well. His opinion that the Bair Hugger "functions much like a household vacuum cleaner" and will "entrain particles from the floor" is not backed by any calculation of the air velocity necessary to displace bacteria-carrying particles (in the range of 4 to 20 microns) from a surface. For his "exposure

[192] Koenigshofer Dep. (DX 39) at 87:5–8.

[193] *Id.* at 69:24–70:9.

estimate," he assumed an extraordinarily contaminated operating room using data from a 1968 study that is no longer in print.[194] Finally, when asked what basis he has for concluding that particle counts are an appropriate surrogate for airborne bioburden, he responded "Well, first of all, I'd rely on common sense."[195] "Common sense" may be an appropriate basis for a lay opinion, but not for an expert. Finally, Koenigshofer's criticism of the Bair Hugger intake filters, without having reviewed any of the test reports showing that they meet the same efficiency standard as the operating room ventilation filters, must be excluded as ill-informed and simply incorrect.

B. Mr. Buck's Testimony Must Be Excluded for Methodological Flaws and a Lack of "Fit."

As noted, Mr. Buck's experiment found that the Bair Hugger emitted thousands of tiny particles that are too small to carry bacteria. Because he did not take any measures to prevent contamination of the Bair Hugger blanket and hose by his own shed skin cells, the small number of larger particles they found are as likely—in fact, more likely—to have come from their bodies as the Bair Hugger. In any event, since he did not attempt to detect bacteria among *any* of the particle emissions, the entire exercise suffers from a lack of "fit": it does not "tend[] to make a fact more or less probable than it would be without [it]." Fed. R. Evid. 401. Mr. Buck's entire testimony is therefore irrelevant under Rule 401, inadmissible under Rule 402, and should be excluded under *Daubert.*

[194] *Id.* at 255:4–24.

[195] *Id.* at 211:18–24.

C. Dr. Apte's CFD and Dr. Elghobashi's Testimony Must Be Excluded as Unreliable and Likely to Mislead the Jury.

Defendants have already shown that the Apte CFD model, based as it is on Dr. Elghobashi's "thought experiment," is fundamentally unreliable and inadmissible. We do not dispute that CFD evidence can be admissible, if properly supported by reliable boundary conditions. *See, e.g.*, *Quiet Tech. DC–8, Inc. v. Hurel–Dubois UK Ltd.*, 326 F.3d 1333, 1343–44 (11th Cir. 2003) (admitting CFD model of jet engine over challenge to expert's inputs and equations). But while the factual basis of an expert's opinion is often a matter of credibility, not admissibility, his testimony must still be excluded if it is "so fundamentally unsupported that it can offer no assistance to the jury." *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996); *accord In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 614 (8th Cir. 2011). In this case, the boundary conditions for Dr. Apte's model are so far from reality as to merit outright exclusion. *Cf. In re Baycol Prod. Litig.*, 596 F.3d 884, 892 (8th Cir. 2010) (affirming exclusion of expert's opinion because it "simply lacks the factual basis to rise above the level of speculation").

There is another very important reason to exclude Dr. Apte's model and Dr. Elghobashi's testimony. Among the stills from Dr. Apte's computer simulation, the graphic that plaintiffs most want to show the jury is this one:[196]

[196] Elghobashi Rept. (DX 57) at 54.

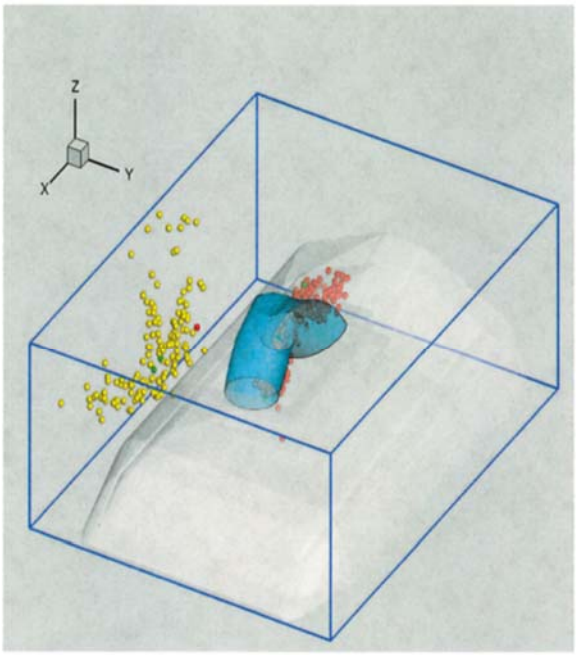

Figure 28: Zoom-in showing the instantaneous snapshot of squames near the surgical site at $t = 27$s.

In this figure, Dr. Elghobashi purports to show bacteria-carrying squame particles invading the patient's surgical wound. This is the only "evidence" that Plaintiffs can offer of contaminated particles actually reaching the surgical site. Of course, that evidence is based entirely on a speculative "thought experiment" lacking any validation from actual real-world measurements. But after hearing Dr. Elghobashi's credentials, the jury might forget that this "supercomputer calculation" is not much more than an "artist's rendering"—especially when confronted with the hardships suffered by an injured plaintiff. As Judge Kyle held in the *Werth* case:

> There can be little doubt that Plaintiffs' experts hold impressive credentials, including two with doctorate degrees from Stanford University and a third who is a former NASA scientist. Moreover, the circumstances giving rise to this case are undoubtedly tragic—a baby badly burned less than a day after birth, in the very hospital where he was born. In light of these sad facts and the experts' qualifications, it is not difficult

> to conceive that a jury would blindly accept Plaintiffs' causation theory while overlooking the shaky foundation upon which it rests.

Werth, 856 F. Supp. 2d at 1067. For the same reason, the Court should exclude Dr. Apte's CFD model and Dr. Elghobashi's testimony under Rule 403. *See Daubert*, 509 U.S. at 595 (stating that "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it"); *United States v. Blade*, 811 F.2d 461, 465 (8th Cir. 1987) (recognizing that expert testimony enjoys an "aura of special reliability," so "the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises more control over experts than over lay witnesses"). Dr. Elghobashi's impressive credentials should not be allowed to disguise the lack of scientific rigor underlying his opinions.

D. Dr. David's Testimony Regarding Plaintiffs' Mechanistic Theories Must Be Excluded for Lack of Expertise, Unreliable Methodology, and an Insufficient Factual Foundation.

Dr. David's testimony establishes that he is unqualified to opine about risk in the clinical setting, let alone the risks associated with the Bair Hugger system, a device he knew nothing about before this litigation. Moreover, Dr. David bases his general causation opinions on the same suite of Augustine-backed research that Plaintiffs' other experts rely on, none of which supports the claim that the Bair Hugger causes surgical infections. His general causation opinions must therefore be excluded.[197]

[197] As noted above, defendants have moved to exclude the remainder of Dr. David's opinions and testimony in a separate motion.

Dr. David had no meaningful experience with the Bair Hugger system, or any of the other patient-warming technologies that are the subject of his opinions in his Report.[198] He has never substantively encountered the Bair Hugger system in his professional capacity, and outside of the work he has done in this case, has never researched, presented on, operated, or otherwise examined the Bair Hugger technology.[199] Dr. David's biomedical engineering experience does not qualify him to opine on issues of medical causation. *See Barrett v. Rhodia, Inc.*, 606 F.3d 975, 982–83 (8th Cir. 2010) (excluding engineering expert whose opinion included pinpointing the cause of Plaintiff's injury).

The Court should also exclude Dr. David's causation opinions because they are not the product of reliable methodology. Dr. David purports to have performed a "Review of Literature," but as shown, his literature review overlaps considerably with the studies cited in Plaintiffs' Master Long Form Complaint. Although an expert may, in the right circumstances, support a causation opinion by "examin[ing] literature in one's field" and providing a "thorough account" of that literature, *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1042–43 (D. Minn. 2013), an expert may not opine about causation "based on an indiscriminate literature review" that is "beyond the scope of [the expert's] expertise," *Smith v. Rasmussen*, 249 F.3d 755, 758 (8th Cir. 2001). In this vein, courts across the country have excluded opinions based upon unreliable literature reviews, where experts have cherry-picked the studies on which they relied. *See In re Rezulin Prods. Liab.*

[198] *See* David Dep. (DX 60) at 11:4–17, 17:20–19:24, 20:5–8.

[199] *Id.* at 13:18–25, 17:3–19, 19:15–24, 23:2–10, 201:22–202:16.

Litig., 369 F. Supp. 2d 398, 425-26 (S.D.N.Y. Mar. 14, 2005) (excluding Plaintiffs' experts whose literature review overlooked studies contrary to their opinions and "discussed only the evidence they believed would advance the plaintiffs' position") (citing *Lust by & Through Lust v. Merrell Dow Pharms.*, 89 F.3d 594 (9th Cir. 1996) (affirming district court's exclusion of evidence on grounds, among others, that the expert had "'pick[ed] and chose[n]' from the scientific landscape")); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1086–87 (D. Kan. 2002) ("[s]elective reliance . . . 'is not generally accepted practice' . . . . [O]btaining information from sources that support, refute or are neutral regarding the hypothesis is appropriate to minimize the likelihood of a false conclusion"), *aff'd*, 356 F.3d 1326 (10th Cir. 2004). Here, Dr. David's literature search was "indiscriminate," and he cherry-picked the studies he chose to rely on. Even a casual search should have retrieved some of the numerous articles finding no increase in bacteria during use of the Bair Hugger system. A literature review performed with ill-defined, unverifiable search terms that fails to produce any articles contrary to Plaintiffs' position must be described as "indiscriminate." *Smith*, 249 F.3d at 758. It certainly cannot be viewed as a "thorough account." *See Block*, 937 F. Supp. 2d at1043. As such, Dr. David's literature search does not reflect a reliable methodology for arriving at a causation opinion, and his testimony should be excluded.

Finally, much of Dr. David's testimony is based on an incomplete appreciation of the record. Like Mr. Koenigshofer, Dr. David has not seen any of the test reports confirming that Bair Hugger filters meet the MERV 14 efficiency standard—the same level

of filtration that ASHRAE recommends for operating room air handlers.[200] If he had, he might have a better understanding of the features of the Model 500 series filters:

> Q. Have you seen a 500 series filter?
>
> A. I don't know what you mean by "seen." I saw a drawing and I saw pictures in brochures.
>
> Q. Okay. Do you recall what shape it is?
>
> A. It's different than the 750.
>
> * * *
>
> Q. You only looked at a drawing of the 500 series filter. Is that correct?
>
> A. Right.
>
> Q. Okay. Do you recall what shape it was?
>
> MR. BANKSTON: Object to the form.
>
> A. Yeah.
>
> BY MS. EATON:
>
> Q. What shape was it?
>
> A. Square.[201]

In fact, the Model 500 series filter—which Dr. David discusses at length in his critique of "The Bair Hugger's Troubling Regulatory History"—is a cylinder.[202]

IV. PLAINTIFFS' ENGINEERS' OPINIONS SHOULD ALSO BE EXCLUDED UNDER MINNESOTA STATE LAW.

The engineers' opinions and testimony should also be excluded under Minnesota law because they lack the "foundational reliability" and "general acceptance" required by

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[200] *See* David Dep. (DX 60) at 235:9–20.

[201] *Id.* at 315:20–316:2; 316:22–317:7.

[202] *See* http://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Bair-Hugger-500-Series-Replacement-Filter-Model-90009?N=5002385+3294259572&rt=rud (last visited September 4, 2017).

the *Frye-Mack* standard. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). Plaintiffs' theories have already been shown to lack a reliable foundation. In addition, a scientific theory is not admissible under Minnesota law unless and until it has gained general acceptance in the relevant medical or scientific community. *See id.*; *see also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming district court's determination that plaintiff's expert's general causation theory is not generally accepted). As detailed above, the engineers' general causation theories have not been generally accepted, and in fact are against the great weight of medical opinion today. Plaintiffs' engineers' opinions and testimony should therefore be excluded under Minn. R. Evid. 702 and *Goeb v. Tharaldson*.

CONCLUSION

Plaintiffs' engineering experts, whose opinions are inescapably tied to Dr. Augustine's flawed and biased studies, have not adduced relevant and reliable evidence of a causal mechanism. Moreover, even if their testimony were admitted, it would fail to advance Plaintiffs' general causation case beyond a mere possibility. Therefore, the engineers and their theories should be excluded as unreliable, unhelpful, speculative, irrelevant, and likely to sow confusion under Federal and Minnesota Rules of Evidence 402, 403, 702, *Daubert*, and *Goeb v. Tharaldson*.

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Respectfully submitted,

s/Peter J. Goss

Jerry W. Blackwell
MN Atty ID No. 0186867
Peter J. Goss
MN Atty ID No. 0267910
Benjamin W. Hulse
MN Atty ID No. 0390952
Mary S. Young
MN Atty ID No. 0392781
Attorneys for Defendants 3M Company and Arizant Healthcare Inc.
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
T: (612) 343-3200 F: (612) 343-3205
blackwell@blackwellburke.com
pgoss@blackwellburke.com
bhulse@blackwellburke.com
myoung@blackwellburke.com

Bridget M. Ahmann
MN Atty ID No. 016611x
Attorney for Defendants 3M Company and Arizant Healthcare Inc.
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
T: (612) 766-7000 F: (612) 766-1600
bridget.ahmann@faegrebd.com